EXHIBIT B

Controlled Substances Act:

21 U.S.C. 802. Definitions:

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.[1]

~~**21 U.S.C. 826(a)(1). Production quotas for controlled substances:** The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II . . . to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.~~[2]

[1] Although Plaintiffs do not believe that quoting the definitions in 21 U.S.C. § 802(10), (11), and (21) is necessary, Plaintiffs do not oppose inclusion of these definitions if the court chooses to quote statutory provisions. If the Court does include such definitions, however, it may wish to also consider including the definition of "opiate" or "opioid" in 21 U.S.C. § 802(18), which states that "[t]he term 'opiate' or 'opioid' means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability." The Court may also wish to consider including the definition of "suspicious order" found in 21 U.S.C. § 802(57) ("[t]he term 'suspicious order' may include, but is not limited to- (A) an order of a controlled substance of unusual size; (B) an order of a controlled substance deviating substantially from a normal pattern; and (C) orders of controlled substances of unusual frequency."), although the Court should note that this statutory provision did not become effective until October 24, 2018, after Plaintiffs filed their original complaints in these actions.

[2] Plaintiffs would oppose inclusion of this provision in the jury instructions for the reasons set forth in their Objection to Defendants' Response ("Objection").

21 U.S.C. 842(a)(1). Prohibited Acts B: It shall be unlawful for any [~~manufacturer,~~ [3]distributor, or dispenser of controlled substances] to distribute or dispense a controlled substance in violation of section 829 of this title.

21 US.C. 829(a)(1). Prescriptions: Schedule II Substances. [N]o controlled substance in schedule II, which is a prescription drug . . . may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed . . . ~~by the Secretary~~ by regulation . . . such drug may be dispensed upon oral prescription ~~in accordance with section 503(b) of that Act~~.[4]

Regulations issued to administer Controlled Substances Act:

21 C.F.R. 1306.04(a). Purpose of issue of prescription: A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. ~~The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.~~ An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of ~~[~~[the CSA]~~section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances~~.[5]

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[3] Manufacturers are not defendants in Track Three, such that this provision seems unnecessary.

[4] Plaintiffs object to the use of statutory cross-references or terms that have not been explained in the instructions, and would be needlessly distracting and confusing. Plaintiffs also note that if Defendants' language were used, it would also be necessary to cite 21 U.S.C.A. § 829(b), as Defendants also sold Schedule III drugs such as hydrocodone before its rescheduling. *See* 21 U.S.C.A. § 829(b) ("Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug . . . , may be dispensed without a written or oral prescription . . . ."). As set forth in Plaintiffs' Objection, the provisions Plaintiffs identified, but Defendants omitted, would also need to be included.

[5] Plaintiffs believe that in light of arguments Defendants have made, and will likely continue to make, but this Court has rejected, they may confuse the jury if the redlined portion of this provision is quoted without further instruction. If it were quoted, it would also be necessary to instruct the jury that "[e]mployment of a pharmacist does not relieve a pharmacy or pharmacy owner of the obligation to ensure that only valid prescriptions are filled." Opinion and Order denying Defendants' motion to dismiss, Dkt. 3403 at 13-25; *see also Linden Med. Pharm. v. Ohio State Bd. of Pharm.*, 2001 Ohio App. LEXIS 2041, at *24 (Ohio Ct. App. 11th Dist. May 8, 2001) (explaining that the Ohio Administrative Code "places the ultimate responsibility upon the 'registrant' … to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs" and that "licensees electing to operate a business through employees are responsible to the licensing authority for their conduct").

21 C.F.R. 1301.71. Security requirements generally.[6]

~~(a)~~ All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. ~~In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in Secs. 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.~~

~~(b) Substantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:~~

~~(a) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);~~

~~(b) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);~~

~~(c) The quantity of controlled substances handled;~~

~~(d) The location of the premises and the relationship such location bears on security needs;~~

~~(e) The type of building construction comprising the facility and the general characteristics of the building or buildings;~~

~~(f) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;~~

~~(g) The type of closures on vaults, safes, and secure enclosures;~~

~~(h) The adequacy of key control systems and/or combination lock control systems;~~

~~(i) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;~~

~~(j) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;~~

[6] Plaintiffs would oppose inclusion of the provisions shown in redline herein in the jury instructions for the reasons set forth in their Objection.

The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and

(15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

21 C.F.R. 1301.72(a). Physical security controls for non-practitioners [such as distributors]:[7]

Schedules I and II. . . . [C]ontrolled substances listed in Schedule I or II . . . shall be stored in one of the following secured areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii)Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

[7] Plaintiffs would oppose inclusion of this provision in the jury instructions for the reasons set forth in their Objection.

~~(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;~~
~~(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;~~
~~(v) The door of which vault is equipped with contact switches; and~~
~~(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.~~

~~21 C.F.R. 1301.73. Physical security controls for non-practitioners[.]~~[8]

~~All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following . . . .~~

21 C.F.R. 1301.74. Other security controls for non-practitioners[.]

~~Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.~~[9]

~~(b)~~(a) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

~~21 C.F.R. 1301.75. Physical security controls for practitioners.~~[10]

[8] Plaintiffs do not believe this provision is necessary in light of the allegations at issue.

[9] Plaintiffs do not, at present, believe that this provision has any relevance to this case, and therefore oppose its inclusion in jury instructions. If, however, this provision becomes relevant based on the evidence introduced at trial, Plaintiffs would not oppose its inclusion. Plaintiffs also believe that the language in their proposal is important to include in the jury instructions.

[10] Plaintiffs would oppose inclusion of this provision in the jury instructions for the reasons set forth in their Objection.

~~(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.~~

~~(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.~~

~~21 C.F.R. 1301.76. Other security controls for practitioners.~~[11]

~~(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.~~

~~(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:~~

~~(1) The actual quantity of controlled substances lost in relation to the type of business;~~
~~(2) The specific controlled substances lost;~~
~~(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;~~
~~(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,~~
~~(5) Whether the specific controlled substances are likely candidates for diversion;~~
~~(6)~~(1) ~~Local trends and other indicators of the diversion potential of the missing controlled substance.~~

[11] Plaintiffs do not, at present, believe that this provision has any relevance to this case, and therefore oppose its inclusion in jury instructions. If, however, this provision becomes relevant based on the evidence introduced at trial, Plaintiffs would not oppose its inclusion.